

21 January 2019: no 1

Brexit and other complications

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EDITORIAL

This first HTB in 2019 leads with several articles linked to the impending Brexit crisis.

A study from the BMJ reports scant plans for health provision if there is a no-deal Brexit and both the UK-CAB and a joint statement from BHIVA, BASHH, HIVPA and NHIVNA recommend that HIV positive people ensure they have sufficient HIV medications to cover the immediate period after 29 March 2019.

While the joint statement recommendation is that one month's supply might be sufficient, the UK-CAB more cautiously recommends getting your standard prescription renewed slightly earlier if this is due to run out in March or April 2019.

Also in the treatment access section, an important modelling paper from Andrew Phillips and colleagues finds that the benefits of universal use of a combination of dolutegravir/TDF/lamivudine in sub-Saharan Africa outweighs the risks, including potential for neural tube defects in infants if dolutegravir is taken by women at conception.

We review three papers on HIV complications: (i) weight gain and integrase inhibitors, (ii) biological vs chronological ageing and (iii) frailty and HIV. These are evolving issues that show HIV management is still complex.

There is also good news in the expansion of trial places for the PrEP IMPACT Trial, reduced HIV incidence in transgender people in the US and the latest US State to update HIV transmission legislation to include that HIV treatment prevents transmission.

And although January is usually a difficult month, we would like to highlight the ongoing i-Base appeal that helps keep our reporting independent and our publications free to UK clinics.

SUPPLEMENTS

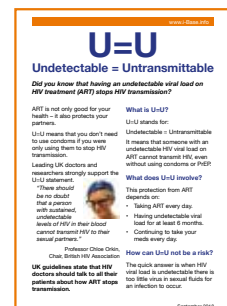
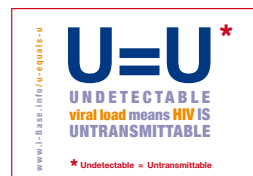
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i-Base 2019 appeal

This year we are continuing a funding appeal to help i-Base continue to provide free publications and services.

Your help has been inspiring – and we hope this support will continue during 2019. If 1000 people support us with £5 a month we will be on course to meet our funding shortfall.

All help is appreciated.

<http://i-base.info/i-base-appeal-we-need-your-help>

TREATMENT ACCESS

BMJ survey reports lack of NHS planning for Brexit: impact on drug supplies unknown

Simon Collins, HIV i-Base

A report in the BMJ reports a lack of comprehensive or consistent planning for Brexit across the NHS. [1]

This includes crucial areas such as continued supply of medicines and implications of immigration changes on the NHS workforce.

Results were from a survey to all NHS trust and health boards across the UK, using freedom of information requests.

Main findings include:

- Only 9% of trusts in England (15/161 that responded, out of a total of 231) have new structures in place to oversee plans for Brexit.
- This compares to 66% of health boards in Wales, Scotland and Northern Ireland (14/21 that responded, out of a total of 25).
- Only 25% of trusts have a risk assessment plan (47 out of 182 that responded).
- Individual trusts report different approaches to government requests not to stockpile medicines or to write longer prescriptions. For example, some trusts are expecting potential interruptions in treatment of six weeks and others for 12 weeks.
- A lack of centralised NHS leadership - with the Department for Health and Social Care for England pushing responsibility for planning to individual trusts.
- Centralised support from the Scottish government is likely to have helped with local planning.
- Even where plans were in place, most were limited due to the uncertainty of any details for a planned Brexit.

C O M M E N T

Guidelines for implications of Brexit for HIV positive people were recently published by the UK Community Advisory Board (UK-CAB), a national network of HIV treatment advocates. [2]

These include asking people to have sufficient HIV medications to cover the months either side of the proposed date for Brexit. HIV medicines are commonly prescribed for six months, which will hopefully cover any short-term interruptions in drug supply and the period when the NHS is most likely to be stressed by changes.

The lack of planning is directly related to the unknown outcomes from not yet having a structured plan to leave the EU, although any of the outcomes where the UK leaves the EU (soft, hard or no-deal) are all likely to damage the NHS, compared to remaining in the EU.

References

1. Iacobucci G. NHS trusts struggle to produce Brexit plans amid continuing uncertainty. BMJ (20 December 2018). <http://www.bmj.com/content/363/bmj.k5346>
2. UK-CAB recommendations on Brexit, HIV and access to HIV medications. (19 December 2018). <http://i-base.info/htb/35483>

UK-CAB statement on Brexit and access to medicines

Simon Collins, HIV i-Base

On 19 December 2018, the UK-CAB, an HIV treatment advocacy organisation, published recommendations to minimise the risk for HIV positive people having an interruption in supply of medicines, due to uncertainty over plans for Brexit. [1]

The guidelines suggest having sufficient medicines to cover the initial few months from April 2019. They suggest arranging this in plenty of time, to reduce pressure on NHS services at the proposed date for Brexit.

The recommendations are posted below.

UK-CAB statement on Brexit, HIV and access to medicines

As a peer-led HIV advocacy project, the UK-CAB, like many other organisations, is concerned about the impact Brexit will have on access to medicines.

Leaving the EU has the potential to increase the costs of medicines to the NHS, restrict rapid access to new medicines and interrupt supplies of currently approved drugs. The last few weeks have been particularly worrying given the limited planning within the NHS.

As no one can predict what will happen after the proposed leaving date of 29th March 2019, the following recommendations are suggested for HIV positive people to be as prepared as possible for any minor disruptions.

1. Check now how much medication you have at home. Count the boxes you have and work out how long it will last you.
2. If your meds are due to run out before the end of April, it would be better to organise a new prescription in or before March. This will avoid pressuring the NHS when services will be least certain. It will also ensure your treatment will be arranged to cover the first few months after March 2019.
3. Check the date of your next clinic appointment and bring this forward if necessary. Please leave enough time for your blood results and meds to be issued well before the end of March.
4. There is no need to ask for an extra supply. Your normal prescription should cover any initial disruption during the first months after April 2019.

Everyone hopes any supply issues, if they arise, will be temporary and short-lived. However, it is in everyone's best interests to be prepared.

HIV treatment in the UK remains free at the point-of-care to anyone with HIV regardless of nationality or residency status.

The UK-CAB will continue to seek updates from the relevant authorities and will post further updates when we know more.

Source

UK Community Advisory Board (UK-CAB) announcement. UK-CAB statement on Brexit, HIV and access to medicines. (19 December 2018).

BASHH, BHIVA, HIVPA and NHIVNA statement on a no-deal Brexit

Joint press release

The following statement was issued by four professional HIV organisations on clinical approaches to a no-deal. It optimistically suggests that pharmaceutical companies will carry the burden of planning and that HIV positive people only need to make sure they have a one-month buffer supply.

Statement

In 2018 the Department for Health and Social Care, in preparation for a no deal Brexit, wrote to pharmaceutical companies that supply UK medicines from, or via, Europe. Companies have been asked to stock at least six additional weeks supply, over and above their business as usual stocks, by 29 March 2019. We are confident this extra stock will allow usual duration prescriptions for everyone, even if there are short-term supply issues after March. Additional contingency planning has assessed specific antiretrovirals at risk.

Trust pharmacies, home delivery companies and community pharmacy partners should not stockpile additional antiretrovirals beyond business as usual stock - pharmaceutical companies are responsible for holding extra supplies. Clinicians do not need to issue longer, or earlier than usual, prescriptions and patients should be reassured that there is no need for concern about the supply of their medication and therefore no need to stockpile. Changes to predicted use of drugs could risk continuity of supply.

As is normal current practice, patients should be advised to ensure they have a buffer supply of medication to last one month beyond their next clinic appointment and to ensure their appointment is booked to reflect this.

Reference

BASHH, BHIVA, HIVPA and NHIVNA statement on management of antiretroviral supplies in preparation for a no-deal Brexit Scenario (11 January 2019).

<https://www.bhiva.org/management-of-antiretroviral-supplies-in-preparation-for-a-no-deal-Brexit-scenario>

Model predicts benefit of dolutegravir for all in sub-Saharan Africa outweighs risk

Polly Clayden, HIV i-Base

A policy where a regimen tenofovir, lamivudine, and dolutegravir is given to all adults on ART, regardless of viral load suppression and intention to have children, provided better health outcomes than policies restricting its use.

These findings, from a modelling study, authored by Andrew Phillips from University College London and colleagues were published online 29 November in the Lancet HIV.

The study used an existing individual-based model of HIV transmission progression and the effect of ART. The model is based on sub-Saharan Africa. The aim was to help inform policy makers on approaches to dolutegravir (DTG) provision that are likely to lead to the greatest health gains at a population level.

For each scenario, the authors considered the situation in 2018 and compared outcomes with potential ART regimen policies over a 20-year time frame.

The different regimen policies included in the model were:

- Tenofovir (TDF), lamivudine (3TC) and efavirenz (EFV) for all
- TDF, 3TC and DTG dependent on viral suppression and intention to have (more) children
- TDF, 3TC and DTG dependent on intention to have children
- TDF, 3TC and DTG dependent on viral suppression only

TDF, 3TC and DTG for all

The authors assumed a rate of reaching a point of intention to have no more children to be 0.005 per 3 months from 25 years. This resulted in 16% of women aged 15–55 years not intending to have children.

They also assumed that women who do not intend to have more children are able to access contraception and its efficacy is 80% (50% in sensitivity analysis).

For acquisition of resistance they assumed a 13 times lower rate of resistance to DTG than to EFV.

They assumed double the risk of neurological toxicity with EFV versus DTG and 1.5 higher potency for DTG versus EFV.

Excess risk of neural tube defects in infants born to women receiving DTG was assumed to be 0.58% (4/596, 0.67% minus 0.09% background rate in HIV negative women).

They also considered different rates of viral load implementation and regimen switch after viral load failure.

Health outcomes were measured in disability adjusted life-years (DALYs). Although these were modelled in adults only, the authors considered DALY effects of neural tube defects and vertical transmission of HIV.

The model revealed, a mean of 98% of people receiving ART over 20 years would be expected to receive DTG with a policy of TDF, 3TC and DTG for all, versus 43% if people with viral load greater than 1000 copies/mL on previous first-line and women who intended to have children were not included in the policy. With policies dependent on intention to have more children and viral suppression only, the respective proportions receiving DTG would be 54% and 85%.

With TDF, 3TC and DTG for all, DTG-related neural tube defects would occur in 0.6%, compared to 0.2%, 0.3% and 0.52% where policies depend on viral suppression and intention to have children, intention to have children only, and viral suppression only, respectively. But vertical transmission risk would be lower with TDF, 3TC and DTG for all, occurring in 2.8%, compared to 3.9%, 3.8%, 2.9% with the respective restrictions.

Providing TDF, 3TC and DTG for all was predicted to lead to more DTG resistance compared with restriction dependent on viral load suppression: 6.7% vs 4.4%. By the end of the 20-year time frame these proportions were: 9.4% vs 7.6%.

The number of deaths due to AIDS among people receiving ART declined with increased use of TDF, 3TC and DTG. Use of TDF, 3TC and DTG for all was predicted to lead to the most DALYs averted, 58,200 vs 22,300 for a scenario with DTG restriction dependent on viral suppression and intention to have more children.

Providing TDF, 3TC and DTG for all was also the most cost effective and would be cost saving over a 20 year horizon.

The authors concluded that using a standard DALY framework to compare health outcomes from a public health perspective, the benefits of transition to TDF, 3TC, and DTG for all substantially outweighed the risks.

Polly Clayden is also a co-author on this paper.

C O M M E N T

These modelled projections are updated as more data from sub-Saharan Africa becomes available – for example this includes information from the NAMSAL study, conducted in Cameroon.

More data from trials conducted in the region, as well as more on the risk of neural tube defects will become available this year.

Reference

Phillips AN et al. Risks and benefits of dolutegravir-based antiretroviral drug regimens in sub-Saharan Africa: a modelling study. Published online 29 November 2018 [http://dx.doi.org/10.1016/S2352-3018\(18\)30317-5](http://dx.doi.org/10.1016/S2352-3018(18)30317-5).

SIDE EFFECTS & COMPLICATIONS

Are integrase inhibitors linked to weight gain? – an evidence review

Polly Clayden, HIV i-Base

HIV treatment with integrase inhibitors appears to lead to greater increases in body weight than with other antiretrovirals. The effect seems to be more pronounced for women and black people. There also might be an additional effect with NRTIs. But it is unclear yet whether these changes are clinically significant.

Andrew Hill from University of Liverpool, Laura Waters from Mortimer Market Centre, London and Anton Pozniak from Chelsea and Westminster Hospital, London, reviewed the evidence to date for integrase inhibitor-associated weight gain. This review was published in January 2019 in the Journal of Virus Eradication. [1]

The authors reported that in 2017–2018, results from four observational cohort studies – conducted in France, Brazil and the US – suggested that integrase inhibitors were associated with greater increases in body weight, particularly among women.

The observational studies were not randomised so differences between antiretrovirals in weight gain might be explained by other factors. Hill et al noted that analysing weight change in randomised trials might be more informative.

Results from five randomised studies support the association between integrase inhibitors and weight gain. Two studies have looked at raltegravir (RAL) and three dolutegravir (DTG). One study also included bictegravir (BIC).

In the ACTG 5257 trial, including 1809 participants, those randomised to first-line RAL-based ART were significantly more likely to become either overweight or obese compared to people receiving either atazanavir/ritonavir (ATV/r) or darunavir/ritonavir (DRV/r) – both in regimens with tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC). Black participants were 55% more likely to become either overweight or obese than white participants.

These weight changes appeared to be associated with abdominal fat, as there was a greater increase in waist circumference among participants treated with RAL.

Results from the NEAT 001 study show greater increases in visceral fat for people treated first-line with RAL plus DRV/r, compared with DRV/r plus TDF/FTC.

SPRING-1 – the original dose-ranging trial of DTG, including 120 participants – reported greater increases in body weight for first-line ART in people randomised to the DTG arm compared with those receiving efavirenz (EFV) – both with two NRTIs.

In the NEAT-022 trial, 415 participants, stable on a two NRTI plus PI-based ART, were randomised to continue the PI or to switch to DTG. There were statistically significant increases in weight for people who switched to DTG, but the difference between the arms was only 1 kg.

The Gilead 1490 trial randomised 631 participants to first-line ART with two different integrase inhibitors. This study was typical of registrational trials and conducted in a mainly white, male, asymptomatic population with high baseline CD4 cell counts.

Mean increase in body weight to week 96 was similar in the two arms: 3.5 kg weight gain with bictegravir (BIC) compared with 3.9 kg with DTG – both combined with tenofovir alafenamide (TAF)/FTC. Hill et al suggested that, if there is an effect of dolutegravir on weight gain, this is likely to be similar with BIC.

Three other studies suggest that there may be an additional effect of NRTIs on weight gain.

In the AMBER trial, there was a greater increase in weight for participants receiving first-line ART with TAF/FTC/DRV/c (1.8 kg) compared with TDF/FTC/DRV/c (0.8 kg).

Results from a German cohort study found mean increase in body weight of 2.3 kg after switching from TDF to TAF.

The STEAL study, which evaluated a randomised switch to either abacavir (ABC) or TDF, found increases in body weight were 1 kg greater in the ABC arm at week 96.

TDF/FTC is known to reduce levels of total cholesterol, which might be associated with changes in body weight.

These three studies showed smaller increases in body weight for TDF/FTC compared to other NRTIs. Hill et al noted that at present it is not clear whether the other NRTIs are contributing to increases in body weight, or if TDF/FTC leads to decreases in body weight.

The authors explained that the observational studies and randomised trials in this review have been analysed using a range of methods and propose using categorised measures of BMI increase (eg from normal to overweight, or from overweight to obese), assuming that body weight is measured at the start and end of treatment.

They note that the FDA consider a 5% loss in weight to be clinically significant and suggest that if a treatment increases mean weight by at least 5%, this would also be clinically significant.

From this review, Hill et al draw the conclusion that it is currently unclear whether integrase inhibitors cause clinically significant changes in body weight (at least 5%), or whether these changes are statistically significant but small (less than 5%).

They stress that the effects of integrase inhibitors on body weight need to be analysed for women, by ethnicity, and the potential additional effects of NRTIs must also be evaluated. The endpoint used in these analyses should follow FDA guidelines where feasible and analyses should also include a range of laboratory markers of cardiovascular risk.

C O M M E N T

It is important to note that when the authors of this review searched for articles on body weight with integrase inhibitors they found no published data from the original phase 3 trials of dolutegravir: SINGLE, ARIA, FLAMINGO, SPRING-2 or GEMINI.

It seems that body weight was not measured prospectively in these studies so they were unable to evaluate the risk of clinical obesity. The publications from the main phase 3 clinical trials of elvitegravir, RAL and BIC do not include any information on body weight either.

And, as usual, the majority of people in phase 3 randomised trials of integrase inhibitors are white and male and results to date suggest that integrase inhibitor-associated weight gain might be greater in women and black people.

Ongoing African studies – including ADVANCE, NAMSAL and DoIPHIN 1 and 2 – comparing DTG to EFV, with predominately black and female populations, have started reporting results or will do so this year. [2] These studies will provide more information on whether or not this potential effect differs by sex and ethnicity.

Clearly this phenomenon need to be carefully monitored given the widespread introduction of DTG globally.

Changes in body weight (and shape) are difficult for patients to report because many doctors see this as being driven to lifestyle factors (diet, exercise etc).

These studies suggest a sufficient signal for significant weight gain to be reported to drug safety and surveillance databases, included the UK Yellow Card Scheme. [3]

References

1. Hill A et al. Are new antiretroviral treatments increasing the risks of clinical obesity? *Journal of Virus Eradication* 2019; 5: e45–e47. http://viruseradication.com/journal-details/Are_new_antiretroviral_treatments_increasing_the_risks_of_clinical_obesity^
2. HIV i-Base. Adult and paediatric optimised ART trial tracker. <http://i-base.info/op-art>
3. UK Yellow Card Scheme <https://yellowcard.mhra.gov.uk>

HIV associated with higher biological age compared to chronological age

Simon Collins, HIV i-Base

A new prospective cross-sectional cohort study reports that people older than 45 commonly have a higher biological age compared to their chronological age, and that the difference is higher for HIV positive people compared to a matched HIV negative control group.

The study was reported by Davide De Francesco and colleagues from the COBRA collaboration and published in the journal AIDS.

The analysis included 134 HIV positive participants on suppressive ART, 79 lifestyle-comparable HIV-negative participants >45 years old, and a further control group of 35 age-matched blood donors (who are screened for other infections and social and lifestyle behaviour, including sexual risk and travel).

Biological age was calculated using 10 age-related biomarkers that have been previously shown to be best predictors of chronological age in a large European study. Results were adjusted for HIV history (CD4, CD8, viral load, ARVs) and other health-related social demographics including age, sex, sexuality, education, smoking, alcohol and recreational drugs, CMV, HBV and HCV.

All HIV positive participants were on effective ART with undetectable viral load (<50 copies/mL), with median CD4 count of 618 (IQR: 472 to 806) cells/mm³. Approximately one third had a history of previous AIDS.

The HIV positive participants had an average biological age that was 13.2 years older than their chronological age (95%CI: 11.6 to 14.9) compared to a biological age in the HIV negative control group that was 5.5 years older (95%CI: 3.8 to 7.2), both $p < 0.001$. Biological age was also significantly higher for both groups compared to the blood donor controls whose biological age was -7.0 years younger than their chronological age (95%CI: -4.1 to -9.9) (both $p < 0.001$).

Higher biological age was significantly associated with chronic HBV ($p=0.008$), higher anti-CMV IgG titer ($p=0.002$) and higher CD8 T cells ($p=0.02$), independently of HIV status.

Among HIV positive participants, multivariate analysis showed CD4 nadir <200 cells/mm³ was associated with biological age increase of 3.5 years (95%CI: 0.1 to 6.8).

The only HIV drug that was significantly associated with higher biological age (by 0.1 (95%CI: 0.06–0.2) years for each additional month of exposure) was the protease inhibitor saquinavir. There was a lack of association with mitochondrial toxic ARVs (d4T, ddI and ddC). However, the discussion in the paper notes this might be a limitation of the biomarkers (as there was also no association with current or past cigarette smoking).

The paper concludes that the results show HIV is more associated with accentuated rather than accelerated ageing, but that longitudinal follow-up is required to really answer this question.

The paper defined accentuated ageing as an increased burden of ageing-related damage while the year-on-year damage remains static over time. Accelerated ageing is defined as occurring when age-related complications occur earlier than expected with a progressive increase in the rate of decline.

Reference

De Francesco D et al on behalf of the Co-morbidity in Relation to AIDS (COBRA) Collaboration. Do people living with HIV experience greater age advancement than their HIV-negative counterparts? AIDS 33(2); 259–268. doi: 10.1097/QAD.0000000000002063. (01 February 2019). Full open access.

<https://journals.lww.com/aidsonline/pages/currenttoc.aspx>

https://journals.lww.com/aidsonline/Fulltext/2019/02010/Do_people_living_with_HIV_experience_greater_age.9.aspx

Frailty in older HIV positive people: independent associations with serious morbidity and mortality

Simon Collins, HIV i-Base

Frailty is a critical age-related risk that over the last ten years has increasingly been highlighted as an important factor in older people living with HIV. [1, 2, 3] A new analysis from the US MACS by Sean Kelly and colleagues reports independent associations between frailty and cardiovascular disease (CVD), bone disease, diabetes and mortality. [4]

The study included 821 men and 195 women >40 years who were enrolled between 2013-14. Median age was 51 years (IQR: 46 to 56), median CD4 count 621 cells/mm³ (IQR: 52 to 827) and 91% had undetectable viral load on ART). Other

demographics included 48% white, 29% Black and 23% Hispanic/other, with 39% defined by BMI as overweight and 28% obese.

Frailty was defined as having three or more of the five frailty Fried criteria. [5]

At baseline 62 (6%) of the cohort were defined as frail and 390 (38%) as pre-frail (meeting 1-2 criteria). By week 48, a further 194 participants (19%) progressed to frailty due to changes in the following criteria: weight loss (n=22), low physical activity (n=53), exhaustion (n=72), grip weakness (n=80), and slow gait speed (n=26).

During a median follow-up time of 4.0 years, highest event rates were reported for diabetes and bone disease (see Table 1) both occurring after a median 23 months follow-up.

In adjusted multivariate analysis, baseline frailty was associated with both new onset diabetes and CVD with a trend towards bone events. An increase in frailty from baseline to week 48 was significantly associated with mortality, but was not associated with incident CVD, diabetes, or bone events. See Table 1. Baseline pre-frailty was not significantly associated with any of the clinical outcomes.

Of the frailty criteria, gait speed, a strong predictor of mortality in older HIV negative adults was most associated with diabetes (p=0.03) and CVD (p=0.06).

Although prevalence of frailty was relatively low at baseline in this population with well-controlled HIV the results support frailty assessment in older HIV positive people.

Frailty can be stopped or reduced by management that includes physical training to increase strength, balance and physical activity. Structured exercise programmes can improve weight, strength, and cardiorespiratory fitness, and reduce the number of frailty criteria.

The study concludes that such interventions are low-risk and, at minimum, may improve health outcomes directly consequent to frailty.

Table 1: Event rates during follow-up

Condition	No. events	adj. IRR (95%CI)	p	Med time to event
Diabetes	84	2.29 (1.03 to 5.10)	0.04	23 months
Bone disease	61	2.31 (0.96 to 5.52)	0.06	23 months
CVD	43	3.83 (1.59 to 9.23)	0.003	21 months
Death	27	3.78 (1.52 to 9.39)	0.004	48-week analysis

References

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<https://www.ncbi.nlm.nih.gov/pubmed/15031310>

TREATMENT GUIDELINES

US adult HIV guidelines updated (Oct 2018)

Simon Collins, HIV i-Base

The most recent update to the main US treatment guidelines were published last year.

All changes are highlighted in yellow in the main document and summarised with an introduction.

Main updates to antiretroviral drug use include:

- Adding ibalizumab (IBA), recently approved for use in persons with multidrug-resistant HIV.
- Bictegravir and doravirine are added to recommended options for first-line therapy
- FDCs containing elvitegravir/c have been reduced to alternative options.
- Dual therapy with dolutegravir/lamivudine is recommended when abacavir, TDF or TAF cannot be used
- Information added on risk of neural tube defects with dolutegravir in early pregnancy

Reference

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (October 2018)

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0>

TRANSMISSION & PREVENTION

NHS England doubles places on IMPACT PrEP study to 26,000

Simon Collins

On 11 January 2019, NHS England agreed that enrolment to the PrEP IMPACT study can be expanded from 13,000 to 26,000 places by 2020. [1]

This decision reverses previous statements that the upper limit for the study was fixed. So far over 10,000 participants have enrolled since the study opened in October 2017. This early demand meant that many sites were fully enrolled within a few months, and many people in need of PrEP

Although it is good that more people might be able to access free PrEP, this study is also controversial for being seen as a way to delay NHS approval.

While NHS England had agreed to fund both drugs costs and some running costs, local authorities will still have to agree to the increased numbers.

C O M M E N T

It is good that enrollment has been expanded but the IMPACT study is not a substitute for NHS England commissioning open access across the country. Even with low barriers to join the study, there are many towns and cities that do not have study sites. [2]

A press statement from National AIDS Trust, emphasised the long-standing community demand to expand the study numbers and that it has been completely unacceptable to see people in need of PrEP being turned away from clinics. [3]

PrEP is already available in Wales and Scotland in programmes that are not capped.

References

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<https://www.england.nhs.uk/2019/01/update-on-the-prep-impact-trial/>
2. PrEP IMPACT study website
<https://www.prepimpacttrial.org.uk/>
3. NAT press statement. NHS hope to double capacity of prep trial after huge demand for hiv prevention drug. (11 January 2019).
<https://www.nat.org.uk/press-release/nhs-hope-double-capacity-prep-trial-after-huge-demand-hiv-prevention-drug>

UK annual HIV surveillance data published - full reports

Simon Collins, HIV i-Base

The full annual HIV surveillance data in the UK for 2018 from Public Health England (PHE) have now published. This includes results by demographic characteristics and geographical region. [1, 2]

These comprehensive reports continue to show that HIV incidence is now falling across the UK and in most demographics.

The data expand on the preliminary results published in September 2018 that were previously reported in HTB. [3]

C O M M E N T

Some community concerns with the way these data were first presented [3] have been considered in the final reports, but these reports still lead with an outdated narrative that is skewed towards condom-use for HIV prevention.

The lack of any significant discussion about the impact of U=U in the one-sentence section on treatment as prevention makes these reports out of step with one of the most significant changes in public health.

References

1. Public Health England. Progress towards ending the HIV epidemic in the United Kingdom 2018 report – summary, key messages and recommendations. (16 pages).
<https://www.gov.uk/government/publications/hiv-in-the-united-kingdom>
2. Public Health England. Progress towards ending the HIV epidemic in the United Kingdom 2018 report. (67 pages).
<https://www.gov.uk/government/publications/hiv-in-the-united-kingdom>
3. Collins S. HIV diagnoses in UK drop for third year: among all ages, risk groups, and ethnicities and across most UK regions. HTB September 2018.
<http://i-base.info/htb/34962>

US CDC updates HIV rates in transgender people

Simon Collins, HIV i-Base

A new CDC analysis has reduced the estimated HIV prevalence among transgender women but shows rates are still high - and also provides first estimates for rates in trans men.

The analysis is important for providing the first update since 2008 in this population where limited data can be used to limit provision of health services.

Results were compiled from a systematic data review of 88 mainly cross-sectional studies from 2006 to 2017 that included both laboratory confirmed diagnoses and self-report studies.

Overall HIV prevalence estimates from laboratory-confirmed studies was 9.2% (95%CI: 6.0% to 13.7%) with 14.1% (95%CI: 8.7% to 22.2%) for transwomen and 3.2% (95%CI: 1.4% to 7.1%) for trans men.

Self-reported HIV rates overall were 16.1% (95%CI: 12.0% to 21.2%) with 21.0% (95%CI: 15.9% to 27.2%), and 1.2% (95%CI: 0.4% to 3.1%) for transwomen and transmen, respectively.

Subgroup analyses by race showed estimates were highest among black people (44%; 95%CI: 23% to 67%).

Participation in sex work was also very high - estimated overall at 31% but significantly higher for transwomen (38%) vs 13% in transmen.

Reference

Becasen JS et al. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017, *American Journal of Public Health* 109, no. 1 (January 1, 2019): pp. e1-e8. DOI: 10.2105/AJPH.2018.304727

<https://www.ncbi.nlm.nih.gov/pubmed/30496000>

Michigan State updates HIV disclosure laws to reflect impact of effective ART

Simon Collins, HIV i-Base

On 8 January 2019 the outdated HIV disclosure law in the US State of Michigan has been modernised.

Previously, a person living with HIV could face a felony up to four years in prison for not disclosing their HIV status prior to any type of sexual penetration. The degree of risk of HIV transmission was not a factor in the statute; including whether or not HIV transmission occurred, or any risk of HIV transmission.

The amendment recognises that people on effective ART with undetectable viral load are not a risk for transmitting HIV. It also narrows the scope of sexual activities subject to prosecution, from “any type of sexual penetration to only “vaginal and anal sex.” Oral sex is also no longer subject to prosecution.

For HIV positive people who are not on treatment and not virally suppressed, non-disclosure remains a felony if HIV is sexually transmitted. If they do not disclose and do not transmit, the penalty has been reduced to a misdemeanor in the amended statute. Any person with a “specific intent” to infect another person also remains subject to prosecution.

Reference

Michigan makes strides in modernising HIV disclosure law. LA Times, (8 January 2019).

<https://www.latimes.com/politics/essential/la-pol-ca-essential-politics-updates-gov-brown-downgrades-from-felony-to-1507331544-htmlstory.html>

OTHER NEWS

Activists announce alternative 2020 conference in Mexico City

An alliance of HIV activists, who focus on key populations affected by HIV that are likely to face entry restrictions for a US-based conference, has announced plans for a international community-led conference titled HIV2020: Community Reclaiming the Global Response.

The event is scheduled to take place in Mexico City, 6-8 July 2020, and will run at the same time as the 2020 International AIDS Conference which will be taking place in the United States.

The HIV2020 Alliance decided to organise the community-led event to provide a safe alternative for individuals who cannot or will not attend AIDS2020 due to discriminatory US immigration and travel policies directed to people from Muslim, African, Caribbean and Latin American countries, people who use drugs, sex workers, and transgender people. The announcement of the event comes on the advent of Human Rights Day, as the conference aims to offer new opportunities to reaffirm the leading role communities can and should play in the global fight for sexual health and human rights.

When the IAS hosted their last event in the U.S. in 2012, sex worker activists and people who used drugs organised their own events in India and Ukraine in protest. In fact, key populations have been organising their own pre-conferences at IAS events to specifically address the needs of their communities for over a decade.

For more details please see the meeting website.

www.hiv2020

ON THE WEB

Conference abstracts

20th International Workshop on Co-morbidities and Adverse Drug Reactions in HIV

Abstracts presented at the 20th International Workshop on Co-morbidities and Adverse Drug Reactions in HIV. *Antiviral Therapy* 2018; 23 Suppl 1: A1-A68

<https://www.intmedpress.com/journals/avt/abstract.cfm?id=3272&pid=88>

Chemsex: online resources

A call to action for effective responses to problematic chemsex

A position paper from organisers and participants of the 2nd European Chemsex Forum, Berlin 22-24 March 2018

<https://ihp.hiv>

Sunshine on a rainy day: Crystal methamphetamine use among gay and bisexual men in Perth

Report on chemsex use among gay men in western Australia.

<http://unsworks.unsw.edu.au/fapi/datastream/unsworks:52871/bin91c217fc-ad08-477c-84de-9e351be878f8?view=true>

Chemsex First AID: a community booklet

A booklet from advocates Ignacio Labayen de Inza and David Stuart about how to react when things go wrong in a chemsex session.

The guide has four sections:

- (i) GHB/GBL-related emergencies.
- (ii) Methamphetamine- and mephedrone-related emergencies.
- (iii) Other emergencies that occur in chemsex environments.
- (iv) A summary of first aid situations.

The guide also considers withdrawal, particularly from GHB/GBL, and the risks of intravenous drug use, such as intravenous infection, HIV infection or introducing a large amount of air into a vein.

[https://www.davidstuart.org/Chemsex First Aid action sheet.pdf](https://www.davidstuart.org/Chemsex%20First%20Aid%20action%20sheet.pdf) (PDF)

TAGline: Intellectual Property and Access

TAGline Fall 2018

As the Trump administration makes noise about the high price of pharmaceuticals while doubling down on its commitment to “protect the engine of American ingenuity,” this issue of TAGline dives deep into the rhetoric and realities of intellectual property (IP) protections.

It also looks at the current wave of political shenanigans on critical drugs, surfacing the fundamental lies and vested interests that deny medication to those in need in the United States and around the world.

http://www.treatmentactiongroup.org/sites/default/files/fall_2018_tagline_final.pdf (PDF)

Influencing and monitoring PEPFAR country programmes

Health GAP has launched the 2019 edition of a Rough Guide to Influencing and Monitoring PEPFAR Country Programmes.

This report is an activist’s tool for watchdogging the world’s largest source of funding for the global HIV response.

<https://healthgap.org/resources>

<https://healthgap.org/wp-content/uploads/2018/12/2019-PEPFAR-Watch-Activist-Guide-1.pdf> (PDF)

PUBLICATIONS & SERVICES FROM i-BASE

i-Base website

All i-Base publications are available online, including editions of the treatment guides.

<http://www.i-Base.info>

The site gives details about services including the UK Community Advisory Board (UK-CAB), our phone service and Q&A service, access to our archives and an extensive range of translated resources and links.

Publications and regular subscriptions can be ordered online.

The Q&A web pages enable people to ask questions about their own treatment:

<http://www.i-base.info/qa>

i-Base treatment guides

i-Base produces six booklets that comprehensively cover important aspects of treatment. Each guide is written in clear non-technical language. All guides are free to order individually or in bulk for use in clinics and are available online in web-page and PDF format.

<http://www.i-base.info/guides>

- Introduction to ART (May 2018)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (November 2016)
- HIV testing and risks of sexual transmission (June 2016)
- Guide to changing treatment and drug resistance (Dec 2017)
- Guide to HIV, pregnancy & women's health (December 2015)

Pocket guides

A series of pocket-size concertina folding leaflets that is designed to be a very simple and direct introduction to HIV treatment.

The five pocket leaflets are: Introduction to ART, HIV and pregnancy, ART and quality of life, UK guide to PrEP and HCV/HIV coinfection.

The leaflets use simple statements and quotes about ART, with short URL links to web pages that have additional information in a similar easy format.

U=U resources for UK clinics: free posters, postcards and factsheets

i-Base have produced a new series of posters, postcards and leaflets to help raise awareness about U=U in clinics.

This project was developed with the Kobler Centre in London.

As with all i-Base material, these resources are all free to UK clinics.

Until our online order form is updated to include the U=U resources, more copies can be ordered by email or fax.

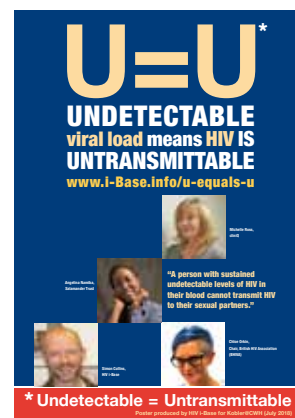
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Order publications and subscribe online

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<http://i-base.info/order>





h-tb

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<http://www.i-Base.info>

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- **Booklets about HIV treatment**

ART in pictures: HIV treatment explained (<i>June 2017</i>): 32-page A4 booklet	quantity _____
Guide to hepatitis C coinfection (<i>April 2017</i>): 52-page A5 booklet	quantity _____
UK Guide To PrEP (<i>November 2016</i>): 24-page A5 booklet	quantity _____
Introduction to ART (<i>September 2016</i>): 48-page A5 booklet	quantity _____
HIV and quality of life: side effects and long-term health (<i>Sept 2016</i>): 96-page A5	quantity _____
Guide to HIV testing and risks of sexual transmission (<i>July 2016</i>): 52-page A5 booklet	quantity _____
Guide to HIV, pregnancy and women's health (<i>November 2015</i>): 52-page A5 booklet	quantity _____
Guide to changing treatment: what if viral load rebounds (<i>Nov 2017</i>): 24-page A5	quantity _____

- **Other resources**

U=U resources:

A3 posters	quantity _____	A5 leaflets	quantity _____	A6 postcards	quantity _____
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